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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,917	01/11/2001	Ashok Tehim	T8466360US3	9294

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EXAMINER

HUANG, EVELYN MEI

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 01/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/758,917

Applicant(s)

TEHIM ET AL.

Examiner

Evelyn Huang

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other:

Art Unit: 1625

1. Claims 1-13 are pending.

***Claim Rejections - 35 USC § 112(2)***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. The term 'suitable' in 'suitable carrier' is vague. Its replacement with --pharmaceutically acceptable -- is recommended.
- b. Claim 6, the compound, '5-amino-n-butylnaphthalimide' has not antecedent basis in claim 1 wherein amino is not in the definition of R2 or R3.
- c. Claims 5-8, 13, please clarify for the examiner the structural difference between 'N-{5-nitro-1H-benz[de]isoquinoline-1,3(2H)-dione}-2-aminoethanol' and 'N-(1,3-dioxo-5-nitro-, 1,2, 3, 4,-tetrahydrobenzo[I]isoquinoline)aminoethanol'.
- d. Claims 10-11, 'neurotropin-mediated activity' is vague since it includes directly or indirectly related conditions at different levels of the physiological cascade. What are these activities?

The rejection is applicable to claims dependent on the above claims.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1625

4. Claims 1-3, 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Costi. The pharmaceutical composition comprising compound 4 (page 1012) is encompassed by the instant claims. The intended use fails to demarcate the instant from the prior composition comprising the same compound. ✕

5. Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Sestanj I (3821383, PTO-1449). The pharmaceutical composition for treating neuropathy (column 1, line 14) comprising 1,3-dioxo-1H-benz[de]isoquinoline-2(H)-acetic acid, 6-bromo-1,3-dioxo-1H-benz[de]isoquinoline-2(H)-acetic acid, or 5-nitro-1,3-dioxo-1H-benz[de]isoquinoline-2(H)-acetic acid (Table, column 4) is encompassed by the instant claims. The method of using the prior art compound to treat neuropathy in the patient would inherently inhibit neurotropin-mediated activity as recited in the instant. ✕

6. Claims 1-4, 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Malizia (EP 206322, PTO-1449) or Semenovich (DE 2521139, PTO-1449). The pharmaceutical composition for treating neuropathy comprising N-(2-carboxy)-ethyl-1,8-naphtalenimide (Malizia, page 12, claim 1) or the compound of formula 1a (Semenovich, page 1) is encompassed by the instant claims. The method of using the prior art compound to treat neuropathy in the patient would inherently inhibit neurotropin-mediated activity as recited in the instant. ✕

7. Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Sestanj II (4254109, PTO-1449). The pharmaceutical composition for treating neuropathy (column 1, line 23) comprising 6-chloro-1,3-dioxo-1H-benz[de]isoquinoline-2(H)-acetic acid, or 6-phenylthio-1,3-dioxo-1H-benz[de]isoquinoline-2(H)-acetic acid (Table, column 5) is encompassed by the instant claims. The method of using the prior art compound to treat neuropathy in the patient would inherently inhibit neurotropin-mediated activity as recited in the instant. ✕

8. Claims 1-3, 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Brana I (4204063). The anti-tumor composition comprising a compound of Example 3, 4, 5 (column 2) ✕

Art Unit: 1625

or 7 (column 3) is encompassed by the instant claims. The intended use fails to demarcate the instant from the prior composition comprising the same compound.

9. Claims 1-9, 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Brana II (J. Org. Chem., PTO-1449). The anti-tumor pharmaceutical composition comprising 5-nitro-1,3-dioxo-1H-benz[de]isoquinoline-2(H)-acetic acid (page 1372, Scheme 6, compound 19) is encompassed by the instant claims 1-9. The intended use fails to demarcate the instant from the prior composition comprising the same compound. The ester compound (page 1372, Scheme 6, compound 21) is encompassed by the instant claim 13.

*Claim Rejections - 35 USC § 103*

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sestanji I (3821383, PTO-1449) in view of Bundgaard.

Sestanji discloses a benzoisoquinoline compound useful for treating diabetic neuropathy. A specific compound, 5-nitro- 1,3-dioxo-1H-benz[de]isoquinoline-2(H)-acetic acid, is described (column 4, table).

Sestanji does not describe the ester or amide of the example compound as in the instant. However, ester and amide are art-recognized prodrugs, which are expressly taught by Bundgaard (page 2, 27).

At the time of the invention, one of ordinary skill in the art would be motivated to prepare the ester and amide prodrugs of Sestanji' compound as taught by Bundgaard to arrive at the instant invention with the reasonable expectation of enhancing the delivery of the drug compound.

Art Unit: 1625

12. Claims 1-3, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brana III (4874863, PTO-1449).

Brana generically discloses a bisnaphthalimide with cytotoxic activity (column 1), and the pharmaceutical composition thereof. A specific compound is described (column 3, Example 4).

The prior art compound has a nitro whereas the instant has a hydrogen on the aromatic portion of the molecule. X

However, Brana teaches that nitro and hydrogen are optional substituents leading to an effective anti-tumor compound (column 1, lines 29-30).

At the time of the invention, one of ordinary skill in the art would be motivated to prepare a pharmaceutical composition comprising a compound with a hydrogen instead of nitro as in Brana's example compound to arrive at the instant invention with the reasonable expectation of obtaining an additional anti-tumor composition.

### *Double Patenting*

13. The issue of priority under 35 USC 102(g) and possibly 102(f) of this invention must be resolved. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 USC 132 to either show that the conflicting inventions were commonly owned at the time of the invention when this application was made or to name the prior inventor of the conflicting subject matter. Since the PTO normally will not institute an interference between applications or a patent and an application of common ownership (MPEP 2302), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 USC 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

14. Assuming common assignee, the following rejection is made.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Art Unit: 1625

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

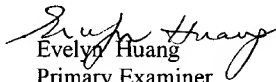
Claims 1-13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the corresponding claims of copending Application No. 09/457606. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are encompassed by the copending claims. *Allowed*

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 703-305-7247. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat can be reached on 703-308-2439. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
Evelyn Huang  
Primary Examiner  
Art Unit 1625

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January 5, 2002